EMPAZIO 10 and 25

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for EMPAZIO 10 and 25[Empagliflozin Tablets 10 mg/25 mg [Film Coated Tablets 10mg and 25 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Empagliflozin is a reversible, highly potent (IC50 of 1.3 nmol) and selective competitive inhibitor of sodium-glucose co-transporter 2 (SGLT2). Empagliflozin does not inhibit other glucose transporters important for glucose transport into peripheral tissues and is 5 000 times more selective for SGLT2 versus SGLT1, the major transporter responsible for glucose absorption in the gut. SGLT2 is highly expressed in the kidney, whereas expression in other tissues is absent or very low. It is responsible, as the predominant transporter, for the reabsorption of glucose from the glomerular filtrate back into the circulation. In patients with type 2 diabetes and hyperglycaemia a higher amount of glucose is filtered and reabsorbed.

INDICATIONS: Empagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes Mellitus.

DOSAGE AND ADMINISTRATION: Type 2 diabetes mellitus: The recommended starting dose is 10 mg empagliflozin once daily for monotherapy and add- on combination therapy with other medicinal products for the treatment of diabetes. In patients tolerating empagliflozin 10 mg once daily who have an eGFR ≥60 ml/min/1.73 m2 and need tighter glycaemic control, the dose can be increased to 25 mg once daily. The maximum daily dose is 25 mg.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients listed.

WARNINGS & PRECAUTIONS: Empagliflozin should not be used in patients with type 1 diabetes mellitus. *Ketoacidosis*, including life-threatening cases, has been reported in diabetes patients treated with SGLT2 inhibitors like empagliflozin. Symptoms such as nausea, vomiting, and confusion require immediate assessment for ketoacidosis, regardless of blood glucose levels. Empagliflozin should be discontinued if ketoacidosis is suspected, and treatment paused during major surgeries or acute illnesses, only restarting when ketones are normal, and the patient stabilizes. *Renal impairment:* Due to limited experience, it is not recommended to initiate treatment with empagliflozin in patients with an eGFR <20 ml/min/1.73 m2. Risk for volume depletion: Based on the mode of action of SGLT2 inhibitors, osmotic diuresis accompanying glucosuria may lead to a modest decrease in blood pressure. Therefore, caution should be exercised in patients for whom an empagliflozin-induced drop in blood pressure could pose a risk. Patients aged 75 years and older may be at an increased risk of volume depletion. Cases of complicated urinary tract infections including pyelonephritis and urosepsis have been reported in patients treated with empagliflozin. Cases of necrotising fasciitis of the perineum, (Fournier's gangrene) have been reported in female and male patients with diabetes mellitus taking SGLT2 inhibitors. An increase in cases of lower limb amputation (primarily of the toe) has been observed in long-term clinical studies with another SGLT2 inhibitor. *Hepatic injury:* have been reported with empagliflozin in clinical trials. A causal relationship between empagliflozin and hepatic injury has not been established. *Chronic kidney disease:* Patients with albuminuria may benefit more from treatment with empagliflozin. Empagliflozin will test positive for glucose in their urine. Monitoring glycaemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG assay. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product.

DRUG INTERACTIONS: Empagliflozin may enhance the diuretic effect of thiazide and loop diuretics, increasing the risk of dehydration and hypotension. It can also increase the risk of hypoglycemia when used with insulin or insulin secretagogues like sulphonylureas, potentially requiring dose adjustments.

Pharmacokinetic Effects: Empagliflozin is metabolized primarily by UGT enzymes and transported by OAT3, OATP1B1, and OATP1B3. Co-administration with inhibitors like probenecid or gemfibrozil may slightly increase empagliflozin levels, but these changes are not clinically significant. *Effects on Other Drugs:* Empagliflozin may decrease blood lithium levels by increasing renal excretion. It does not interact significantly with drugs metabolized by CYP450 or UGT isoforms, and its pharmacokinetics are not affected by drugs like metformin, warfarin, or diuretics. Interaction studies for empagliflozin have been conducted only in adults, and its effects on the paediatric population are not yet known.

ADVERSE REACTIONS: Lactic Acidosis, Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis, Volume Depletion, Urosepsis and Pyelonephritis, Hypoglycemia, Necrotizing Fasciitis of the Perineum (Fournier's Gangrene), Genital Mycotic Infections, Lower Limb Amputation, Hypersensitivity Reactions, Vitamin B_{12} Deficiency. *Very common:* Hypoglycemia, Volume depletion. *Common:* Vaginal moniliasis, vulvovaginitis, balanitis and other genital infection, Urinary tract infection (including pyelonephritis), Thirst, Constipation, Pruritus, Increased urination, Serum lipids increased. Uncommon: Ketoacidosis, Urticaria Angioedema, Dysuria, Blood creatinine increased/Glomerular filtration rate decreased, Hematocrit increased. *Rare:* Necrotizing fasciitis of the perineum and urosepsis. *Very Rare:* Tubulo- interstitial nephritis.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/EMPAZIO (10mg and 25mg)/FEB-2025/01/ABPI

(Additional information is available on request)